REMARKS/ARGUMENTS

Applicant's acknowledge and thank the Examiner for the removal of the rejections under 35 U.S.C. § 102 in response to Applicant's previous reply.

In this Amendment, independent claim 1 is amended to clarify that the mammal has an Aspergillus infection. Thus, the amended claims recite a method for treating an Aspergillus infection in a mammal infected with Aspergillus by administering thymosin alpha 1, which methods are neither disclosed nor suggested by the prior art, as acknowledged in the Advisory Action. Support for this amendment can be found throughout the application as filed, specifically support can be found at paragraphs [0020]-[0021] of the application as filed.

No new matter has been added by way of these amendments. Entry and consideration of this Amendment are respectfully requested.

Response to Rejection under 35 U.S.C. § 103(a)

In the Final Office Action, claims 1-12 are rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Wingard (*Bone Marrow Transplantation* (1997) *19*: 343-347) in view of Knutsen (WO 98/35696).

The Final Office Action asserts that Knutsen teaches a method of preventing Aspergillus infection by administering thymosin alpha 1 (in particular to bone marrow patients), because such is allegedly inherent in administering thymosin alpha 1 to patients. The Examiner also seems to assert, apparently in relation to dependent claims 9-11, that Wingard teaches administering Amphotericin B for treating Aspergillus infection, and thus the combination of thymosin alpha 1 and Amphotericin B would have been obvious.

In the Advisory Action, the Examiner asserts that the art has recognized "the use of both TA1 and Amphotericin B for use in bone marrow transplants." The Examiner also clarifies that "the combination is not based upon the interpretation (relied upon for anticipation rejections) that Knutsen inherently prevents infection, but rather based upon its well known use in the art—stimulation of hematopoiesis." The Examiner

acknowledges that the "Applicant has merely identified a quality TA1 possessed that others have failed to detect" and that "the art has failed to detect its antifungal properties."

While not acquiescing on the merits of the rejection and in an effort to further prosecution, independent claim 1 has been amended. Claim one has been amended to clarify that the claimed method is a method for treating an Aspergillus infection in a mammal infected with Aspergillus by administering thymosin alpha 1. In view of these amendments, the art cited by the Examiner neither teaches nor suggests the use of thymosin alpha 1 for treating an Aspergillus infection in an individual infected with Aspergillus.

Applicants remind the Examiner that under MPEP § 2144.06, pharmaceutical compositions are generally *pima facie* obvious to combine when "two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072. (See, MPEP § 2144.06, Part I.) For the instant application, Wingard teaches administering Amphotericin B to treat Aspergillus infection and Knutsen teaches use of thymosin alpha 1 for promoting stem cell development. Additionally, in the Advisory Action, the Examiner acknowledges that the Applicant has "identified a quality TA1 possessed that others have failed to detect" and that "the art has failed to detect its antifungal properties." As no common purpose is described in the art, the two cannot be combined for a showing of *prima facie* obviousness. In addition, it would have been unexpected to one of skill in the art that thymosin alpha 1 would have any antifungal effects in a composition of Amphotericin B and thymosin alpha 1, further rebutting any arguments for *prima facie* obviousness. Accordingly, the obviousness rejection under 35 U.S.C. § 103(a) is improper, and as such should be withdrawn.

Additionally, the Examiner asserts that Knutsen teaches preventing Aspergillus infection by administering thymosin alpha 1 (in particular to bone marrow patients), because such is allegedly inherent in administering thymosin alpha 1 to patients. The Examiner is respectfully reminded that "[o]bviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established. *In re Rijckaert*, 9 F.2d 1531, 28 USPQ2d 1955 (Fed. Cir. 1993)." (See, MPEP 2141.02 part V. 2141.02, Part V.) In addition, MPEP § 2112 states that "[t]he fact that a certain result or

characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." Citing to *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). (See, MPEP § 2112, Part IV.)

For the present case, neither Wingard nor Knutsen teach treating an Aspergillus infection by administering thymosin alpha 1 to a mammal infected with Aspergillus as is claimed in the currently amended claim set, and the Examiner does not assert as much. In fact, in the Advisory Action the Examiner acknowledges that the Applicant has "identified a quality TA1 possessed that others have failed to detect" and that "the art has failed to detect its antifungal properties." As there are no descriptions of any antifungal properties for thymosin alpha 1 in the art there remains only a ***possibility*** that thymosin alpha 1 would exhibit antifungal properties, which is ***not sufficient*** to establish inherency. (See, MPEP § 2112, Part IV.) As the Examiner's rejection under 35 U.S.C. § 103(a) rely on the alleged inherency of an antifungal property for thymosin alpha 1, such rejection is improper and should be withdrawn.

Based on the above arguments, withdrawal of the rejection under 35 U.S.C. § 103(a) is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants respectfully submit that this application is now in condition for allowance. However, the Examiner is requested to call the undersigned if any questions or comments arise.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§1.16, 1.17, and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 50-1283.

Dated: July 28, 2010

Respectfully submitted,
COOLEY LLP

By: /Christina MacDougall/
Christina MacDougall
Reg. No. 65,210

COOLEY LLP
ATTN: Patent Group
777 6th Street NW, Suite 1100
Washington, DC 20001

Tel: (415) 693-2000
Fax: (202) 842-7899
1187333 v2/SF